



U.S. Department of Justice

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May 6, 2013

**BY ELECTRONIC COURT FILING WITHOUT EXHIBITS
EXHIBITS SUBMITTED BY HAND DELIVERY UNDER SEAL AND EX PARTE**

Honorable Edward R. Korman
Senior United States District Judge
Eastern District of New York
225 Cadman Plaza East
Brooklyn, NY 11201

Re: Tummino v. Hamburg, Nos. 05-CV-366, 12-CV-0763 (ERK/VVP)

Dear Judge Korman:

We write on behalf of defendants in the above-referenced actions, in response to the Court's minute order of earlier this afternoon, which directed the government to provide the Court by close of business today with "Teva's submissions referred to in the second paragraph of the supplement approval letter annexed to the Woodcock declaration." The minute order provided that the "submission may be under seal if the submissions are subject to one of the many 'confidentiality' objections that the defendants have invoked."

Although FDA may publicly disclose certain documents in the application file after a supplemental new drug application is approved, FDA has not yet had the opportunity to review the documents referenced by the Court to assess them for disclosure or to redact privileged and confidential information. FDA may nevertheless disclose Teva's confidential information if Teva consents. Counsel for Teva has advised the government that it objects to the Court's directive to produce the referenced submissions, which are confidential, proprietary, and beyond the scope of this litigation. It nevertheless has authorized the government to provide the documents for the Court's *in camera* review as long as they are not filed in the public court docket or made available to plaintiffs or their counsel.

Hon. Edward R. Korman, United States District Judge
Tummino v. Hamburg, Nos. 05-CV-366, 12-CV-0763 (ERK/VVP)
May 6, 2014
Page 2

On the basis of that authorization, and subject to the objections and points set forth in the government's letters to the Court dated March 14 and 22, 2013, we respectfully provide the requested materials *ex parte* and under seal.

Respectfully submitted,

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By: /s/ {FILED ELECTRONICALLY}
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